

## **REMARKS**

Claims 1-27 are currently pending in the present application. Claims 1 and 12 have been amended to recite that the first holder device is freely slidable along the tubing towards the second holder device and that each holder device is configured to receive at least two of the courses of tubing. No new matter has been added in these changes. Support for the amendments to claims 1 and 12 may be found throughout the specification and in the figures, see for example, page 2, line 20-page 3, line 14 and FIG. 3a. Claim 26 has been amended to provide antecedent basis. Support for new claim 27 may be found throughout the specification, for example, on page 7, lines 18-25 and in FIG. 6.

Applicants respectfully request reconsideration.

### **I. Interview Summary**

Applicants kindly thank the Examiner for the opportunity to discuss the issues in this case.

A telephonic interview was held on November 28, 2006 with Examiner Koharski and Heidi Dare. No exhibit was shown and no demonstration was conducted. U.S. Patent Nos. 5,916,199 to Miles and 5,643,216 to White were discussed. No agreement was reached regarding the claims.

### **II. Claim Rejections 35 U.S.C. § 102(b)**

Claims 1, 3-8, 10-12, 14-19 and 21-26 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Miles (U.S. 5,916,199). According to the Examiner, Miles discloses a tapeless tubing anchoring system for intravenous applications.

Applicants respectfully traverse the Examiner's rejection based on Miles. Applicants respectfully request reconsideration based on the newly amended claims 1 and 12 and the traversals discussed below.

Miles is directed to a tapeless anchoring system comprising a first holder and a second holder. The top surface of the base [of the first holder] has a channel configured to receive a portion of tubing. The interior surface of the bottom portion

[of the second holder] has a channel formed therein. The channel and recess [of the second holder] are configured to cooperate to form an elongated hole configured to removably receive a portion of the tubing. (Abstract.)

As shown in FIG. 1 of Miles, a single course of tubing runs between the holder devices 14 and 16. The portion of the tubing extending from the first holder 14 is folded, however, the courses of the folded tubing at the arrow pointing to 20 and in the holder 14 do not run between the first holder device 14 and the second holder device 16. As shown in FIG. 4 and discussed in the specification, "Top portion 100 of the second holder 16 has a **single** elongated aperture 134 that is configured to be aligned with one of elongated apertures 132 in bottom portion 102 when top portion 100 is removably secured to bottom portion 102 by male connectors 76 and female connectors 78." (Col. 9, line 66-Col. 10, line 4.) The second holder 16 as shown and described in the specification is configured to receive only a single course of tubing and thus, the second holder cannot receive at least two courses of tubing. In addition, since the second holder only receives one course of tubing, it is not possible for essentially parallel courses of tubing to run between the first holder device and the second holder device.

Additionally, it is clear from the summary of the invention of Miles that **anchoring** and fixing the tubing in place on the patient is an object of the invention. As described in the specification: "Another object of the present invention is to provide a tapeless anchoring system capable of securely holding flexible tubing in place on the patient with out causing damage or abrasions to the skin or soft tissue of the patient, pulling the hair of the patient, or otherwise injuring the patient." (Col. 2, lines 58-62.) "A further object of the present invention is to provide a tapeless anchoring system capable of preventing accidental removal of an intravenous needle or catheter, as well as holding the intravenous tubing in place." (Col. 3, lines 4-7.) Miles teaches an anchoring system having two holders that are anchored to the patient and the holders are clearly not configured to be adjustable by being

freely slidable with respect to each other by movement of the tubing along the guides in the first holder device.

In contrast, Applicants' newly amended claims 1 and 12 recite that **each** holder device receives at least two of the courses of tubing. In addition, claims 1 and 12 recite that the device is capable of holding essentially parallel courses of tubing running between the first holder device and the second holder device. Claims 1 and 12 further recite that the first holder device is freely slidable along the tubing towards the second holder device by movement of the tubing along the guides in the first holder device. These limitations are clearly not taught or suggested by Miles.

Therefore, Applicants assert that claims 1 and 12 are clearly not anticipated by Miles. Applicants respectfully request that the rejection of claims 1, 3-8, 10-12, 14-19 and 21-26 have been rejected under 35 U.S.C. § 102(b) be withdrawn.

### **III. Claim Rejections 35 U.S.C. § 103**

#### **A. Claims 2 and 13**

Claims 2 and 13 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Miles in view of Reekie (U.S. 6,105,218). According to the Examiner, Miles meets the claim limitations with the exception of a first holder with multiple bores.

Reekie relates to a snap-type fastening device. Reekie states "It would be desirable to provide a device which can be easily operable using only one hand, to selectively secure elongate members that are joined with the patient to a variety of different types of supports (such as a bed sheet, hospital gown), in a non-obtrusive manner." (Col. 1, lines 36-40.) Reekie further states, "Fastening device 2 is composed of first and second complimentary shaped injection molded plastic members 4 and 6. Member 4 includes first and second partial-cylindrical portions 8 and 10 and member 6 includes complimentary shaped first and second cylindrical portions 12 and 14. Portions 8, 12 and 10, 14 are dimensioned so as to form a 'snap' type of fit when these portions are urged towards each other so that the

partial-cylindrical portions nest or engage one another.” (Col. 2, lines 14-23.)

“[F]astener 2 is closed, so as to selectively engage a sheet material or elongate member within the portions 10, 14, by squeezing the opposite ends of members 4 and 6 together.” (Col. 3, lines 19-22.)

To the contrary, claims 2 and 13, depending from claims 1 and 12, respectively, require a first and a second holder device, each holder device configured to receive at least two courses of tubing. Claims 1 and 12 also each require that first holder device is freely slidable along the tubing towards the second holder device by movement of the tubing along the guides in the first holder device. Applicants assert that claims 2 and 13 are patentable over Miles in view of Reekie.

Furthermore, Applicants respectfully assert that there is no suggestion in the Miles reference to combine the tapeless tubing anchoring system with the snap-type fastening device of Reekie as required by § 103. In fact, Miles teaches away from using a snap-type fastener in describing devices used to stabilize an intravenous apparatus as follows:

“Clips that frictionally hold the tubing in place tend to place a compressive force on the tubing which reduces the flow through the tubing. Some of the devices available include bracelets or strap-like devices in which the flexible tubing is inserted. These devices, however, require the tubing to be in an aperture, which presses down on the tubing, or can be strapped into a bracelet. In either case, compression is being placed on the tubing, thereby reducing the flow at that particular section of the tubing.” (Col. 2, lines 29-38.)

In addition Miles discusses loops of tubing extending from the end of a device. “It is very important that the loop not be occluded or compressed, which would interrupt the supply of fluid. In the prior devices, however, the loop of tubing is unprotected and increases the probability that the loop will become entangled as the patient is moving.” (Col. 2, lines 42-47.) Therefore, combining Miles with the snap-type fastener taught by Reekie is improper.

Therefore, Applicants respectfully request that the rejection of claims 2 and 13 under 35 U.S.C. §103(a) be withdrawn.

**B. Claims 9 and 20**

Claims 9 and 20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Miles in view of White (U.S. 5,643,216). According to the Examiner, Miles meets the claim limitations with the exception of three parallel courses of tubing.

Applicants respectfully traverse the Examiner's rejection based on Miles in view of White since the references alone or in combination fail to teach or suggest a device for subcutaneous supply of a medicament to a patient having a first holder device and a second holder device where the first holder device is freely slidable along the tubing towards the second holder device by movement of the tubing along the guides in the first holder device.

Furthermore, Applicants respectfully assert that there is no suggestion in either reference to combine the tapeless tubing anchoring system with the tooth and groove interference fit bracelet of White as required by § 103. In fact, Miles teaches away from using an interference fit bracelet as discussed above with reference to claims 2 and 13. In the citations above, Miles teaches away from using a bracelet or a device where the tubing is pressed down in an aperture and compression is placed on the tubing, such as the device taught by White. Therefore, combining Miles with the interference fit bracelet of White is improper.

Even if the teachings of Miles and White could be combined, all of the recited elements in Applicants' rejected claims would not be found in the combination. Miles has been discussed above. White teaches securing tubing in the bracelet system that is secured to the patient's appendage. According to the specification, the system provides "a means for securing portions of a medicament delivery system to an appendage of a patient to prevent movement of these portions of the delivery system relative to the appendage thereby preventing accidental removal of the cannulae from the patient." (Col. 1, lines 63-67.) The bracelets of White are secured to the patient's appendage and cannot freely slide towards one or the other bracelet along the tubing. White clearly does not teach or suggest a first holder device where the first holder device is freely slidable along the tubing towards the second holder device by

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movement of the tubing along the guides in the first holder device. White does not make up the deficiencies of Miles.

Therefore, Applicants respectfully request that the rejection of claims 9 and 20 under 35 U.S.C. §103(a) be withdrawn.

#### IV. Summary

Having carefully addressed the Examiner's objections and rejections, Applicants respectfully assert that the application is in condition for allowance. Allowance of the present claims is earnestly solicited.

Should the Examiner wish to discuss any of the above submissions in more detail, the Examiner is asked to please call the undersigned at the telephone number listed below.

Respectfully submitted,



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